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Ethan R. Signer

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

12/11/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/879,329	<b>Applicant(s)</b> SIGNER ET AL.	
	<b>Examiner</b> MARIA B. MARVICH	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This office action is in response to arguments filed 8/31/09. Claims 1-16 and 18-21 are pending in this application.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 8, 10, 12 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Capecchi et al (US 5,464,764; see entire document). **This rejection is maintained for reasons of record in the office action mailed 3/30/09.**

Capecchi et al teach a vector comprising a positive and a negative selectable marker flanked by peptides that each individually expresses a protein (see e.g. figure 1). The flanking sequences can be inverted relative to one another (see e.g. col 8, line 60-62). While figure 1 depicts a vector with just a positive marker, the text teaches that the region can include a positive and a negative selection marker. Cells are selected that express the positive marker and then following a second homologous recombination event, cells lacking the negative and positive marker are screened (see e.g. col 18, line 6-40 and example 8).

### ***Response to Arguments***

Applicants arguments filed 8/31/09 have been considered but are not persuasive.

Applicants argue that the claimed construct differs from that of Capecchi et al in two ways. First, applicants argue that the flanking sequences are direct repeats that each contain a copy of a gene of interest. However, this interpretation is based upon limitations that are not explicitly required of the claims. Rather, the claims recite, "each direct repeat comprising a nucleic acid sequence encoding a peptide wherein the peptide is capable of being expressed in said plant cells". The recitation of "a nucleic acid" encompass simple sequences such as dinucleotides which as demonstrated in figure 6 can encompass for example EcoRI sites which are direct repeats of one another (see figure 5D). Similarly, the recitation that the direct repeats each encode a peptide wherein the peptide is expressed in the cell encompasses Capecchi et al as a peptide can be a dipeptide. While one could interpret the claim to also encompass a situation in which each of the two direct repeats encodes the same gene of interest, the claim language is so broad as to read on additional embodiments. "While it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not itself impose that limitation. A broad interpretation of a claim by USPTO personnel will reduce the possibility that the claim, when issued, will be interpreted more broadly than is justified or intended. An applicant can always amend a claim during prosecution to better reflect the intended scope of the claim." MPEP 2105. In this case, applicants claim language does not direct one to a single interpretation wherein the direct repeats comprise the same gene of interest. Secondly, applicants argue that the positive and negative markers are not both flanked by the repeats. While Capecchi et al does demonstrate in figure 1 a construct in

Art Unit: 1633

which the negative marker is not flanked by the repeats, the disclosure directs one to such an arrangement, " For example, the PNS vector can include a second negative selection marker contained within the third DNA sequence. This second negative selection marker is different from the first negative selection marker contained in the fourth DNA sequence. After homologous integration, a second modified target DNA sequence is formed containing the third DNA sequence encoding both the positive selection marker and the second negative selection marker."

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10-16, 18 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. US Patent No. 6,984,774 B1 in view of Bauer *et al.* US Patent No. 6,534,315

Art Unit: 1633

B1 (previously made of record) and further in view of Lassner et al. US Pub No. 2002/0035739

A1 (previously made of record). **This rejection is maintained for reasons of record in the office action mailed 2/12/08 and 3/30/09.**

Independent claim 1 is directed to a genetic construct for use in transforming host plant cells, comprising: a. a positive selectable marker gene that when transformed into the host plant cells facilitates growth on a positive selective medium that is complementary to the positive selective marker gene, b. a negative selectable marker gene that when rendered operable in the host plant cells hinders growth on a negative selective medium that is complementary to the negative selectable marker, the negative selectable marker being different in kind from the positive selectable marker, and c. two direct repeats of a gene of interest, each direct repeat comprising a nucleic acid sequence encoding a peptide, wherein the peptide is capable of being expressed in said plant cells, with the direct repeats immediately flanking the positive and negative selectable marker genes of (a) and (b). Independent claim 21 is directed to a genetic construct having the limitations of claim 1 and further recites that the negative selectable marker gene is CodA.

In Figure 1, Peterson et al. teaches a genetic construct for transforming host plant cells comprising a positive selectable marker gene that when transformed into host plant cells facilitates growth on a positive selective medium that is complementary to the positive selective marker gene (i.e., NPT II) and two direct repeats of a gene of interest, each direct repeat comprising a nucleic acid sequence encoding a peptide (i.e., GUS), wherein the peptide is capable of being expressed in said plant cells, with the direct repeats immediately flanking the selectable marker gene. (See also column 3, examples B., C. and D. and paragraphs 4-5 in

Art Unit: 1633

column 4.) In the construct illustrated in Figure 1, recombination is detected by reconstitution of the GUS gene, which provides for marker rescue of cells in which recombination has occurred. However, Peterson *et al.* teaches that genes other than marker genes can be used as the gene of interest (see, e.g., the fourth full paragraph in column 5) and teaches detection of marker deletion as an alternative to marker rescue as a means to identify recombination events (see especially column 5, lines 63-67). Thus, Peterson *et al.* teaches a genetic construct comprising all of the elements of the instant independent claims except for an explicit teaching of including a negative selectable marker gene in the region flanked by the direct repeats (claim 1), wherein the negative selectable marker gene is CodA (claim 21), and further suggests marker deletion as a means to detect recombination.

Bauer *et al.* teaches a genetic construct comprising a positive selectable marker gene and a negative selectable marker gene, different in kind from the positive selectable marker, and direct repeats of a gene of interest that flank the positive and negative selectable marker genes (see especially the paragraph beginning at line 34 in column 3 and the paragraph bridging columns 3-4). Furthermore, in the paragraph bridging columns 10-11, Bauer *et al.* teaches a method of removing a selectable marker comprising transforming cells with the genetic construct disclosed therein, identifying transformants using the integration marker (*i.e.*, positive selection marker) and then selecting cells that have lost the negative selection marker by culturing in negative selection medium. (*i.e.*, selection by marker deletion.) Thus, Bauer *et al.* teaches that when recombination events are selected by marker deletion, a negative selectable marker gene is positioned between the direct repeats so that the negative selectable marker gene is deleted by the recombination event.

Lassner et al. teaches, “Examples of negatively selectable markers useful in the context of plant genetic engineering include a number of genes involved in herbicide metabolism, including...codA...” (Paragraph 0033.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the genetic construct of Peterson et al. by the insertion of a negative selectable marker gene between the direct repeats of a gene of interest comprised by the construct as described in the teachings of Bauer et al. One would have been motivated to combine the elements of the prior art because Peterson et al. teaches marker deletion through recombination as an alternative means of identifying cells in which recombination events have occurred and Bauer et al. teaches that detection by marker deletion involves the insertion of a negative selectable marker gene between the direct repeat sequences. One would have been motivated to use marker deletion strategy described by Bauer et al. to carry out marker deletion type detection of recombination events as suggested by Peterson et al. because the process of Bauer et al. was known in the art at the time of invention as an effective means to identify cells comprising recombined constructs.

In view of the foregoing, a genetic construct having all of the limitations of the genetic construct of the instant claim 1 would have been obvious to one of ordinary skill in the art at the time the invention was made. Furthermore, as the method of detecting recombination events described in the paragraph bridging columns 10-11 of Bauer et al. comprises all of the elements of the process recited in independent claim 4, the process of claim 4 would also have been obvious to one of ordinary skill in the art at the time of invention. Still further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the

Art Unit: 1633

teachings of Peterson et al. in view of Bauer et al. to use codA as the negative selectable marker gene because Lassner et al. teaches that codA is a negatively selectable marker gene that was known in the art to be useful for plant genetic engineering. One would have been motivated to use the codA marker gene and one would have had a reasonable expectation of success in using the codA marker gene in view of the teaching of Lassner et al. that the codA gene was established as an effective negative selectable marker useful in plant genetic engineering. Absent evidence to the contrary, one would have a reasonable expectation of success in combining the prior art elements because each of the elements were known to be operative independently and all that is required is that the elements in combination retain their known prior art functions. Thus, the products and processes of independent claims 1, 4 and 21 would have been obvious to one of ordinary skill in the art at the time the invention was made. Furthermore, the limitations of the dependent claims are also found in the cited teachings or would be obvious over the teachings found therein. As described above, Lassner et al. teaches the use of a CodA negative selectable marker according to dependent claims 2, 5, 7, 11 and 16 and Peterson et al. teaches a positive selectable marker that is NPTII according to claim 3. Furthermore, Peterson et al. teaches that the products and processes described therein can be used in many of the species set forth in claim 18. (See especially column 5, lines 30-42.)

Claims 6, 10, 12 and 14 are directed to the genetic construct of claim 1, wherein the positive and negative selectable markers are limited to specific arrangement within the construct with respect to one another (*e.g.*, GI-PS-NS-GI *versus* GI-NS-PS-GI). Claims 14-16 are further limited to comprising additional genes of interest flanking the gene of interest present as a direct repeat. Although Bauer *et al.* does not explicitly teach any particular configuration of the positive

Art Unit: 1633

and negative selectable markers, other than that they should be flanked by the direct repeat, the skilled artisan would not expect that the arrangement of the selectable markers within the boundaries of the direct repeat would affect the function of the construct in any way. A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities because one skilled in the art would be motivated by the expectation that compounds of similar structure will have similar function (see *e.g.*, MPEP 2144.09). Thus, it would be *prima facie* obvious to the skilled artisan to use either of the configurations of positive and negative selectable markers set forth in the claims. With regard to additional genes of interest, Peterson et al. teaches that the recombination constructs might further comprise, at least, a gene encoding a transposase (see especially column 4, lines 59-61). Thus, claims 6, 10, 12 and 14-16 would also have been obvious over the cited art. In view of the foregoing, the invention of claims 1-7, 10-16, 18 and 21, as a whole, would also have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the claims are properly rejected under 35 USC § 103(a).

Claims 1-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (US Patent No. 6,984,774 B1) in view of Bauer *et al.* (US Patent No. 6,534,315 B1) and further in view of Lassner et al. (US Pub No. 2002/0035739 A1) as applied to claims 1-7, 10-16, 18 and 21 above, and further in view of Capecchi et al (US 5,464,764; see entire document). **This rejection is maintained for reasons of record in the office action mailed 3/30/09.**

Art Unit: 1633

Applicants claim a genetic construct for use in transforming host plant cells, comprising:

- a. a positive selectable marker gene that when transformed into the host plant cells facilitates growth on a positive selective medium that is complementary to the positive selective marker gene,
- b. a negative selectable marker gene that when rendered operable in the host plant cells hinders growth on a negative selective medium that is complementary to the negative selectable marker, the negative selectable marker being different in kind from the positive selectable marker, and
- c. two direct repeats of a gene of interest, each direct repeat comprising a nucleic acid sequence encoding a peptide, wherein the peptide is capable of being expressed in said plant cells, with the direct repeats immediately flanking the positive and negative selectable marker genes of (a) and (b).

Independent claim 21 is directed to a genetic construct having the limitations of claim 1 and further recites that the negative selectable marker gene is CodA. Furthermore, the method requires culturing the plants cells on the positive selective medium, selecting TO transformants, regenerating To plants , collecting seed or plant from the Tn generation, germinating the T1 or Tn seeds on the negative selection medium to form seedlings wherein the seedlings contain neither the positive or negative marker.

The teachings of Peterson, Lassner or Bauer are described above and are applied as before except the references do not teach the screening step;

Peterson teaches that the cells are transformed and seeds selected and grown into plants on positive selection media and cells selected that grew on positive selection media to form T1 seeds and plants (see e.g. example 2 and 3). However, Peterson et al does not teach selection in negative media of the T1 plants. Bauer teaches that when the vector comprises a [positive and

Art Unit: 1633

negative marker, the selection proceeds in two steps, first selection in positive media and then using the negative selection marker and thus the markers are deleted.

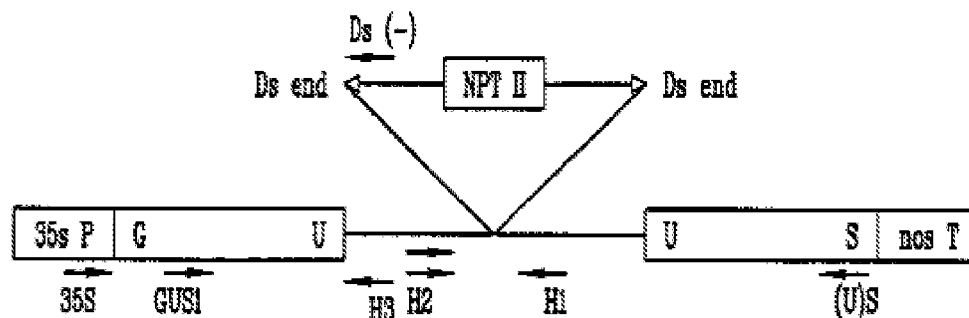
The teachings of Capecchi et al are as above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the provided selection method steps of Capecchi et al with the vectors of Peterson et al in view of Bauer et al because the combination of Peterson et al and Bauer et al teach a configuration of a vector comprising direct repeats flanking a positive and negative selectable marker and because Capecchi et al teach that with such vectors selection proceeds by selecting for the positive marker as set forth in Peterson et al followed by selection for loss of the negative marker wherein the negative and positive markers are also lost. In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court particularly emphasized "the need for caution in granting a patent based on a combination of elements found in the prior art," (Id. At 1395) and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." (Id. At 1395.) In this case, the art of selecting for markers is clearly known and it would have been obvious to use detailed protocols as set forth in Capecchi et al with the known vectors of Peterson et al in view of Bauer et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

***Response to Arguments***

Applicants arguments filed 8/31/09 have been considered but are not persuasive. The claims require that the direct repeats comprise a nucleic acid sequence that encodes a peptide, which as shown above Peterson et al teach. The difference between Peterson et al and the instant claims, aside from the inclusion of a second negative marker, is that the direct repeats do not immediately flank the marker and that the nature of the peptides encoded. There is no indication in the art that placing direct repeat sequences such that they immediately flank the marker is an inventive step in the art. Rather, as regards the positioning of the direct repeats to flank the marker(s) immediately, such a teaching is known and predictable in the art as shown by Bauer et al. Bauer et al teach a construct comprising "a selectable marker, by placing it between two identical direct sequences, termed direct repeat sequences (DRS)". By looking at analogous art, one would examine the nature of the direct repeats for configurations used in the art. In this case, Peterson et al teach the benefit of using direct repeats that encode a peptide.

Specifically, Peterson et al teach a direct repeat comprising a nucleic acid sequence encoding a peptide as depicted below. The middle portion of the GUS sequence flanks the marker. This sequence present on either side of the marker comprises sequences that are direct repeats and that can be expressed in a plant cell.

**Fig.2A**

“A Ds element (courtesy of V. Sundaresan) was inserted between two partially overlapping non-functional segments of the (-glucuronidase gene5 (GUS; courtesy of H. Puchta) to generate a binary plant transformation vector termed GU-Ds-US (FIG. 1). The sequences were prepared according to Tinland et al., 91 Proc. Natl. Acad. Sci. USA 8000 (1994) and the plasmid containing the sequences was called "plasmid GU.US." The homologous direct repeat sequences are 618 bp in length, and the distance between them is 6.3 kb including the 4.6 kb Ds element. “

Applicants argue that the nature of the direct repeats distinguishes Peterson et al from the instant claims in that the direct repeats of Peterson et al do not encode a peptide that is capable of being expressed in the plant cell. However, as one can see above, Peterson et al teach direct repeats encoding the middle portion of GUS. As in the instant case, the peptides are not under operable linkage to a promoter but comprise sequences that are capable of being expressed in a plant cell. In other words, should the sequences above be operable linked to a promoter, each would be capable of being expressed. This is the same criteria used in the specification as neither direct repeat is expressed. Furthermore, the 5' and 3' peptides when operable linked to one another are expressed a GUS. It appears as if applicants are relying on an interpretation that is not explicit in the claims. “Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim

Art Unit: 1633

limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.” *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). See also *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004)(discussing recent cases wherein the court expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment)” MPEP 2111.01. In this case, the ‘U’ portion of each flanking elements is the same peptide and each are “capable” of being expressed in a plant cell. Given the overlapping nature of the teachings, one would have been motivated to look at analogous means of selecting transformation events to improve such methods in predictable ways. IN this case, Bauer et al teach flanking positive and negative markers immediately with direct repeats whereas Peterson et al teach that these direct repeat can comprise sequences encoding peptides. While applicants would like to dismiss the peptide of Peterson et al as not being capable of being expressed in the plant cell, it is not clear given that this is a plant peptide why this would not be the case.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1633

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD  
Primary Examiner  
Art Unit 1633

/Maria B Marvich/  
Primary Examiner, Art Unit 1633